

**Response Under 37 CFR §1.116****Expedited Procedure****Examining Group 1637**

Application No.: 10/566,223

Paper Dated: November 15, 2010

Response to Office Action dated August 19, 2010

Attorney Docket No.: 4544-060174

**REMARKS**

Claims 117-120 and 124-132 are pending in this application. Claims 130-132 have been withdrawn from prosecution as directed to non-elected subject matter. Claim 121-123, 125 and 133-135 have been previously cancelled. Claims 117-120 and 124-132 have been objected to or stand rejected under 35 U.S.C. § 103. In view of the amendments and remarks below, Applicants respectfully request that the objections and rejections be reconsidered and withdrawn.

**OBJECTION TO THE CLAIMS**

Claim 117 has been objected to because it is missing a period at the end of the claim. The claim has been amended to correct this typographical error. Accordingly, withdrawal of this objection is respectfully requested.

**REJECTION UNDER 35 U.S.C. § 103**

Claims 117-120 and 124-129 have been rejected under 35 U.S.C. § 103 as obvious in view of the following combination of references:

Claim(s)	Cited References
117-120 and 124 and 126	Chakravorty <sup>1</sup> , Jaber <sup>2</sup> and Hernstadt <sup>3</sup>
127-129	Chakravorty, Jaber, Hernstadt, GenBank <sup>4</sup> , Marchetti <sup>5</sup> and Buck <sup>6</sup>

On page 13 of the Office Action, the Examiner states that “it is noted that the features upon which applicant relies (i.e., obtaining a pellet containing viable mycobacteria) are not recited in

<sup>1</sup> Chakravorty *et al.*, “Novel use of guanidinium isothiocyanate in the isolation of *Mycobacterium tuberculosis* DNA from clinical material,” FEMS MICROBIOLOGY LETTERS (2001) 205: 113-117 (“Chakravorty”).

<sup>2</sup> Jaber *et al.*, “A simple method of DNA extraction from *Mycobacterium tuberculosis*,” TUBERCLE AND LUNG DISEASE (1995) 76: 578-581 (“Jaber”).

<sup>3</sup> United States Patent No. 6,027,883 to Herrnsstadt *et al.* (“Herrnsstadt”).

<sup>4</sup> GenBank Accession No. U22037 (“GenBank”).

<sup>5</sup> Marchetti *et al.*, “Evaluation of PCR in detection of *Mycobacterium tuberculosis* from formalin-fixed, paraffin-embedded tissues: comparison of four amplification assays,” J. OF CLINICAL MICROBIOLOGY (1998) 36(6): 1512-1517 (“Marchetti”).

<sup>6</sup> Buck *et al.*, “Design strategies and performance of custom DNA sequencing primers,” BIOTECHNIQUES (1999) 27(3): 528-536 (“Buck”).

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the rejected claim(s). .... In this case, claims 117-119 and 124 do not require [a pellet containing viable mycobacteria], and, accordingly, Applicant's argument was unpersuasive."

Applicants have amended claim 117 to further recite "obtaining viable mycobacteria." As previously argued, the cited references are directed to isolating DNA, isolating viable mycobacteria. Thus, claim 117 is patentable over the cited references. Since claims 118-120, 124, 126-129 from claim 117, these claims are likewise patentable over the cited references.

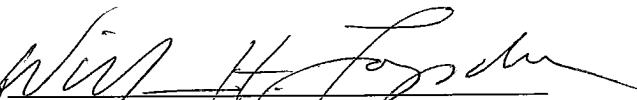
Furthermore, claims 127-129 recite two different primer pairs, (devRf2 / devRr2 and devRf3 / devRr3), for PCR-based amplification of the devR gene from *M. tuberculosis*. In contrast, Chakravorty refers to a completely different primer set that amplifies a 513 base pair DNA fragment.

**CONCLUSION**

Accordingly, claim 117 is patentable over the cited references. Claims 118-120, 124 and 126-129 are also patentable over the cited references by virtue of their dependence on claim 117. Therefore, in view of the amendments to the claims and remarks, Applicants respectfully request that the objections and rejections asserted be reconsidered and withdrawn, and that pending claims 117-120, 124 and 126-129 be allowed. The Applicants further request that claims 130-132 be rejoined and allowed.

Respectfully submitted,

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